

In re Application J. K. MEHRA *et al.*
Metoprolol Manufacturing Process
Application Serial No. 10/807,221

IN THE DRAWINGS

No amendment

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REMARKS

This paper is submitted in response to the 27 December 2005 OFFICE ACTION. This paper being timely submitted, no fee is believed due.

5 Anticipation

All claims stand rejected as anticipated by Sven PALMÉR *et al.*, *Manufacturing Process of Metoprolol*, United States Letters Patent No. 6,252,113 (26 June 2001) or by Josep M. RIBALTA BARO *et al.*, *Industrial Process For Obtaining An Aryloxypropanolumine*, United States Letters Patent No. 5,082,969 (21 Jan. 1992). Reconsideration is respectfully requested.

10 The OFFICE ACTION alleges that claim 1 of the instant application "broadly reads on" RIBALTA BARO's Examples 1-2 and on PALMÉR's Working Example. Whether or not the claim "broadly reads on" a reference, however, is not the applicable legal standard.

Rather, the claim is anticipated if - and only if - "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See
15 *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir., 1987); *see also* *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir., 1989) (the prior art must teach the invention in as complete detail as is contained in the claim).

In the immediate case, claim 1 enumerates six distinct claim elements. In contrast, the OFFICE ACTION fails to allege the presence of each of these elements in either reference. This is
20 not surprising because neither reference in fact teaches every claim element. For example, the OFFICE ACTION correctly fails to allege that RIBALTA BARO's Examples 1-2 teaches claim elements A), C), D) and I). Similarly, the OFFICE ACTION correctly fails to allege that PALMÉR's Working Example teaches claim elements C), D), E), F) and I).

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Further, the prior art must teach each claim element in the arrangement required by the claim. *In re Bond*, 910 F.2d 831 (Fed. Cir., 1990). In the instant case, claim 1 requires reacting a phenol and epichlorhydrin in an alkaline medium:

A) combining 4-(2-methoxyethyl)phenol with epichlorhydrin;

B) reacting said combination of 4-(2-methoxyethyl)phenol and epichlorhydrin in an alkaline aqueous medium;

In contrast, RIBALTA BARO's Examples 1-2 teach reacting a phenol with a sodium-ion donor to make sodium phenolate, and then reacting that sodium phenolate with epichlorhydrin:

A) combining 4-(2-methoxyethyl)phenol with an aqueous sodium-ion containing medium

to make sodium phenolate, *see* col. 2, lines 46-48;

B) reacting said sodium phenolate with epichlorhydrin, *see* col. 2, lines 48-50;

RIBALTA BARO's Examples 1-2 cannot anticipate as a matter of law because it fails to teach the same arrangement required by claim 1. *See In re Bond, supra*.

Withdraw of the anticipation rejections is respectfully believed necessary because the OFFICE ACTION fails to state a *prima facie* case of anticipation.

Obviousness

All claims stand rejected as obvious in light of PALMÉR *combined with* RIBALTA BARO. Reconsideration is respectfully requested.

The OFFICE ACTION alleges that claim 1 of the instant application is "substantially disclosed" in RIBALTA BARO's Examples 1-2 and PALMÉR's Working Example. Whether or not the claim is "substantially disclosed" by the art of record reference, however, is not the applicable legal standard.

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Rather, to establish a *prima facie* case of obviousness, all words in a claim must be considered. *See In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A., 1970). Thus, the combined prior art must teach each and every claim limitation. *See In re Royka*, 490 F.2d 981 (C.C.P.A., 1974).

In the instant case, claim 1 enumerates six distinct claim elements. In contrast, the
5 OFFICE ACTION fails to allege the presence of any of these elements in the combined references.

This is not surprising because the combined references do not teach every claim element. For example, the combined references fail to teach claim elements C), D) and I). Rather, the OFFICE ACTION recognizes that the pH claimed in element C) is "not explicitly disclosed in the examples of the prior art." The OFFICE ACTION fails to state a *prima facie* case because the
10 OFFICE ACTION fails to allege where each and every claim element is taught in the art of record.

Furthermore, even if the prior art teaches the genus, a specific species may be patentable where that species shows unexpected synergy over the disclosed genus. For example, where the prior art teaches that a reaction with "an alkaline chlorine or bromine solution" such as sodium hypobromite will yield 35.4%, achieving an unexpectedly-high yield of 64.3% using sodium
15 hypochlorite is patentable. *In re Meyer*, 599 F.2d 1026 (C.C.P.A., 1979).

Similarly, even if the prior art teaches to use sulfuric acid, a specific concentration of sulfuric acid species may be patentable where that species is critical for the success of the claimed invention. For example, where the prior art teaches that a reaction uses "concentrated sulfuric acid," achieving an unexpectedly-high purity using a specific concentration (98%) of
20 sulfuric acid is patentable. *Akzo N.V. v. United States International Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir., 1979).

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In the instant case, assuming the prior art teaches the genus of solutions with a pH, the inventors allege that they have achieved an unexpectedly-high yield using a solution with the claimed specific pH. This specific pH range therefore appears non-obvious. *See In re Meyer; Akzo v. U.S.*

5 As support for an obviousness rejection, the OFFICE ACTION relies on *In re Aller*, 220 F.2d 454 (C.C.P.A., 1955). Reconsideration is respectfully requested.

In *Aller*, the prior art of record disclosed the same parameters (temperature and sulfuric acid concentrations) claimed by the applicant. *See id.* at 455. In contrast, in the instant case, the claims recite a specific pH range, while the art of record fails to mention any pH range at all.

10 Further, the prior art in *Aller* itself suggested the desirability of modifying the prior art ranges. *See Ex parte Sullivan*, Patent Application Serial No. 09/110,221, (B.P.A.I., 2003), citing *In re Aller*. In the instant case, the OFFICE ACTION does not allege that the art of record mentions pH at all, nor that the prior art suggests modifying any prior art pH range. Thus, *In re Aller* is not controlling.

15 Further, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation, the prior art must teach that the particular parameter at issue is "result-effective," *i.e.*, a variable which achieves a recognized result. For example, in *In re Antonie*, 559 F.2d 618 (C.C.P.A., 1977), the claims covered a water treatment device with a tank volume : contractor area of 0.12 gal./sq. ft. The prior art did not recognize
20 that treatment capacity is a function of the tank volume : contractor ratio. The Circuit Court of Patent Appeals (the predecessor to today's Federal Circuit) held that because that ratio was not recognized in the prior art as a "result-effective" variable, optimizing it is *not* routine.

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In the instant case, the OFFICE ACTION fails to allege that the prior art teaches any particular pH of the reaction mixture *at all*, much less teach that pH is a "result effective" variable. Thus, the art of record fails to suggest modifying that variable in the claimed manner.

Because the OFFICE ACTION fails to allege that the art of record teaches each element of the claims, and because the art of record fails to fairly suggest modifying the prior art in the claimed manner, the OFFICE ACTION fails to state a *prima facie* case of obviousness.

Summary

Applicant respectfully believes the claims are in condition for prompt allowance.

Respectfully Submitted on behalf of Applicant by its attorneys,
PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/

By Mark POHL, Reg. No. 35,325
55 Madison Avenue, 4th floor
Morristown, NJ 07960
(973) 984-0076

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Enclosure:

DECLARATION UNDER 37 C.F.R. RULE 132

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